Remarks

Current Claim Status

Claims 1-24, 41, 44-49, 67, 84, 87-94, and 110 have been canceled previously or herein without prejudice or disclaimer. Applicants reserve the right to pursue subject matter encompassed by all canceled claims in one or more divisional or continuation applications.

Currently pending claims 42, 43, 68, 85, 86, and 111 were withdrawn from consideration by the Examiner (see below).

Claims 33, 34, 36, 37, 43, 50, 52, 60, 62, 63, 69, 76, 77, 79, 80, 86, 95, 103, 105, 106, 112, 113, and 114 have been amended herein (discussed below). No new matter has been added.

Claims 25-40, 42, 43, 50-66, 68-83, 85, 86, 95-109, 111-117 are currently pending.

Restriction Requirement

The previously issued restriction requirement has been made final. *See*, Paper No. 20040610, page 2, part 2.

Withdrawn Claims

The Examiner has withdrawn claims 1, 11, 17-20, 22, 24, 42, 43, 68, 85, 86, and 111 from further consideration "as being drawn to non-elected inventions." *See*, Paper No. 20040610, page 2, part 3.

Applicants have herein canceled, without prejudice or disclaimer, claims 1, 11, 17-20, 22, and 24. Applicants reserve the right to pursue subject matter encompassed by all cancelled claims in one or more divisional or continuation applications.

Applicants respectfully request rejoinder of withdrawn method claims 42, 43, 68, 85, 86, and 111 upon allowance of the claims currently under examination. *See*, Paper No. 20040610, page 2, part 4.

Current Status of Parent Applications

Applicants have been requested to amend the present specification to reflect the status of parent application No. 09/904,615. *See*, Paper No. 20040610, page 2,

part 5. Thus, Applicants have herein amended the specification to comply with this request. Additionally, Applicants have amended the first paragraph of the specification (Cross-Reference To Related Applications) to reflect the status of U.S. Application Nos. 09/739,254 and 09/511,554 (of which the present application also claims benefit under 35 U.S.C. § 120). Applicants have also amended this paragraph to bring it into compliance with recent PTO guidelines. No new matter has been added.

Information Disclosure Statement

The Examiner has indicated "the references cited in the Search Report of EP 99 94 2469 have been considered, but will not be listed...because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing....must be filed within the set period for repy to this Office Action." *See*, Paper No. 20040610, page 2, part 7.

Accordingly, Applicants submit herewith form PTO/SB/08a/b with the listed refererences (as cited in European Search Report of EP 99 94 2469). For the Examiners' convenience, Applicants also submit herewith copies of the four publications cited therein. Additionally, as previously noted in Applicants IDS submission of March 14, 2002, Applicants note that these four publications were cited in a counterpart European patent application in reference to a gene/protein *different* from that to which the claims are drawn in the presently pending U.S. application.

Objection to Claim 13

Claim 13 was objected to "because it is dependent on non-elected claim 11..." *See*, Paper No. 20040610, page 3, part 8. Applicants have herein canceled claim 13. Thus, the objection to this claim is now moot.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 13, 33, 34, 36, 37, 41, 44-50, 52-67, 69-84, 87-110, and 112-117 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." *See*, Paper No. 20040610, page 3, part 10.

(A) Claims 33, 60, 76, 103, and 114 were rejected as allegedly indefinite "because only intact antibody can be human and not an antibody fragment." Further, it was suggested that these claims "be amended to recite, for example, 'The antibody or fragment thereof of claim [X], wherein the antibody is a human antibody'". *See*, Paper No. 20040610, page 3, part 10(A).

Applicants gratefully thank the Examiner for suggesting alternative claim language. However, Applicants must respectfully disagree with the assertion that "only intact antibody can be human". Applicants submit that this interpretation appears to construe the term "human antibody" as limited only to <u>*whole*</u> human antibodies, such as are generated by human B-cells *in vivo* (*e.g.*, a human IgG antibody consisting of 2 heavy chains and 2 light chains). However, Applicants respectfully submit that the limitation "wherein the antibody is a human antibody" should not be so narrowly construed. In contrast, this limitation should merely be understood to indicate that the claimed antibody (whether "whole" or a fragment) was originally derived from immunoglobulin sequences *in the human genome.* As an example of human antibody fragments, Applicants submit herewith Jespers, *et al.*, "Guiding the Selection of Human Antibodies from Phage Display Repertoires to a Single Epitope of an Antigen", Bio/Technology, Vol. 12, (Sept. 1994) (describing a method of engineering fully human Fab antibody fragments).

In view of the Examiner's comments, however, Applicants have herein amended claims 33, 60, 76, 103, and 114 to recite "The antibody or fragment thereof of claim [X] which is human" (instead of "wherein the antibody is a human antibody"). In view of the above explanation and amendments, Applicants respectfully request that the rejection of claims 33, 60, 76, 103, and 114 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

(B) Claims 34 and 77 were rejected as allegedly indefinite "because only [intact] antibody can be a polyclonal antibody and not an antibody fragment." Likewise, it was suggested that these claims "be amended to recite, for example, 'The antibody or fragment thereof of claim [X], wherein the antibody is a polyclonal antibody'". *See*, Paper No. 20040610, page 3, part 10(B).

Again, Applicants thank the Examiner for suggesting alternative claim language. However, Applicants must again respectfully disagree with the assertion that antibody fragments cannot be polyclonal. This interpretation also appears to

construe the term "polyclonal antibody" as limited only to *whole* polyclonal antibodies. However, this limitation should not be so narrowly construed. Rather, this limitation should be understood merely to indicate that the claimed antibody (whether "whole" or a fragment) is comprised of two or more antibodies which bind to the same target antigen but which are comprised of somewhat different amino acid sequences. Hence, a mixture of any two or more Fab fragments (having different amino acid sequences) would constitute an example of polyclonal antibody fragments. For example, a repertoire of human Fab fragments derived from a phage display library (such as described in Jespers, *et al.* (cited above)) constitute an example of polyclonal antibody fragments. As another example, Applicants submit herewith Lang, et al., "Polyclonal preparations of anti-tetanus toxoid antibodies derived from a combinatorial library confer protection", Biotechnology, Vol. 13, pp.683-685 (July 1995) (analyzing *in vivo* therapeutic potential of polyclonal human Fab antibodies).

Again, in view of the Examiner's comments, Applicants have herein amended claims 34 and 77 to recite "The antibody or fragment thereof of claim [X] which is polyclonal" (instead of "wherein the antibody is a polyclonal antibody"). Additionally, Applicants believe it was probably the Examiners' intention to request the same such amendment in "polyclonal" claims 43 and 86. Therefore, Applicants have also made the corresponding amendments in these claims. In view of the above explanation and amendments, Applicants respectfully request that the rejection of claims 34 and 77 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

(C) Claims 50, 93, and 113 were rejected as allegedly indefinite "because only [intact] antibody can be a monoclonal antibody and not an antibody fragment." Likewise, it was suggested that these claims "be amended to recite, for example, 'The antibody or fragment thereof of claim [X], wherein the antibody is a monoclonal antibody'". *See*, Paper No. 20040610, pages 3-4, part 10(B).

Again, Applicants thank the Examiner for suggesting alternative claim language. However, Applicants must again respectfully disagree with the assertion that antibody fragments cannot be monoclonal. This interpretation also appears to construe the term "polyclonal antibody" as limited only to *whole* polyclonal antibodies. However, this limitation should not be so narrowly construed. In like manner to the claim rejections addressed above, Applicants respectfully submit that

the term "monoclonal antibody" should not be narrowly construed to mean *whole* human antibodies. Thus, Applicants note that, for example, a mixture consisting only of Fab antibody fragments which were derived from the same polynucleotide sequence (*i.e.*, having identical amino acid sequences) would constitute a monoclonal antibody fragment.

Again, in view of the Examiner's comments, Applicants have herein amended claims 50, 93, and 113 to recite "The antibody or fragment thereof of claim [X] which is monoclonal" (instead of "wherein the antibody is a monoclonal antibody"). In view of the above explanation and amendments, Applicants respectfully request that the rejection of claims 50, 93, and 113 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

(D) Claims 41, 67, 84 and 110 were rejected as allegedly indefinite. *See*, Paper No.20040610, page 4, part D. Although Applicants do not agree with the basis of the rejection presented. Claims 41, 67, 84 and 110 have been canceled herein without prejudice or disclaimer. Applicants reserve the right to pursue subject matter encompassed by all canceled claims in one or more divisional or continuation applications.

(E) Claims 44-49 and 87-92 were rejected as allegedly indefinite. *See*, Paper No.20040610, page 4, part E. Although Applicants do not agree with the basis of the rejection presented. Claims 44-49 and 87-92 have been canceled herein without prejudice or disclaimer. Applicants reserve the right to pursue subject matter encompassed by all canceled claims in one or more divisional or continuation applications.

(F) Claims 36-37, 62-73, 79-80 and 105-106 have been rejected as allegedly lacking proper antecedent basis in the base claims from which they depend. Applicants thank the Examiner for suggesting alternative claim language which would be deemed acceptable. *See*, Paper No.20040610, page 4, part F. Accordingly, Applicants have herein amended claims 36-37, 62-73, 79-80 and 105-106 as suggested. Therefore, Applicants respectfully request that this rejection be withdrawn.

(G) Claims 13, 69, 87, and 95 were rejected as allegedly indefinite "because ATCC Deposit No. 203081 contain multiple different clones...and it is unclear to which polypeptide the antibody is directed." *See*, Paper No.20040610, page 4, part G.

Applicants note that claims 13 and 87 have been canceled herein. Applicants have also amended pending claims 69 and 95 to specify that the claimed antibodies specifically bind the HUVDJ43 polypeptide encoded by the cDNA contained in ATCC Deposit Number 203081 wherein said HUVDJ43 polypeptide is at least 95% identical to SEQ ID NO:114. Support for this amendment can be found in the specification as filed, for example, at page 182, line 24 to page 183, line 2.

(H) Claim 13 was rejected as allegedly indefinite. *See*, Paper No.20040610, page 4, part H. Applicants have herein canceled claim 13 without prejudice or disclaimer. Accordingly, the rejection of this claim is now moot.

(I)-(J) Claims 52 and 112 were rejected as allegedly indefinite because "SEQ ID NO:2 has only 5 amino acids, [and] it is unclear how SEQ ID NO:2 would comprise at least 30/50 contiguous amino acids. *See*, Paper No.20040610, page 4, parts (I)-(J).

Applicants thank the Examiner for such careful consideration of the claims and, thus, for pointing out the clerical error in claims 52 and 112, wherein "SEQ ID NO:2" should have been "SEQ ID NO:114" (corresponding to the HUVDJ43 polypeptide). Claims 52 and 112 has herein been amended to recite "SEQ ID NO:114" (instead of SEQ ID NO:2). Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 101

Claims 13, 25-41, 44-67, 69-84, 87-110, and 112-117 were rejected under 35 U.S.C. § 101 as allegedly "not supported by either a specific and/or substantial asserted utility or a well established utility." *See*, Paper No.20040610, page 5, parts 5-6. In particular it was alleged that:

> The instant application does not disclose the biological role of the polypeptide or its significance...the specification fails to disclose any particular function or biological significance for SEQ ID NO:114 or antibodies directed to SEQ ID NO:114...No

> single effect of the disclosed Gene No. 48 encoding SEQ ID NO:114, is ascribed to the polypeptides and hence to the antibodies against those polypeptide.

See, Paper No.20040610, pages 5-6, part 6.

The Examiner has also asserted that:

> US 2003/0004311 A1 publication teaches a polypeptide with 99.7% homology to claimed SEQ ID NO:114, with one conservative amino acids difference. The '156 publication further teaches that the reference polypeptide can stimulate the release of TNA-α from human blood, modulate the uptake of glucose or free fatty acid by cells, stimulate or inhibit the proliferation or differentiation of cells or gene expression, stimulate the release of proteoglycans, stimulate the release of cytokine from peripheral blood mononuclear cells, inhibit the binding of A-peptide to factor VIIA, or detect the presence of tumor in a mammal (see entire document). Thus, to employ the claimed antibody in the treatment and/or detection of vascular disorders including vasculitis, cardiovascular disorders such as myocardial infarction, myocarditis, ischemia and stroke would clearly be using it as the object of further research since other cells express the same polypeptide such a blood cells.

See, Paper No.20040610, pages 6, first paragraph (emphasis added).

Applicants respectfully disagree and traverse the rejection. As an initial matter Applicants note that claims 13, 41, 44-49, 67, 84, 87-94, and 110 have been canceled herein. Therefore, the rejection with respect to these claims is now moot.

Second, even assuming *arguendo* that other cells, such as blood cells, do express the polypeptide of the invention this would not result in a *per se* mutual exclusion for use in treating vascular disorders. Moreover, even though the polypeptide of the invention may stimulate release of molecules from blood cells, this does not necessarily mean the polypeptide is *expressed by* blood cells. And, although the polypeptide of the present invention could be used as an object of further research, this should not be held to denote that it does not presently have patentable utility under 35 U.S.C. § 101. If such were the case, compositions of matter would never be patentable, since such are always open to additional avenues of further research.

Applicants also note that when a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown. *Raytheon v. Roper,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 835

(1984); *see also* M.P.E.P. § 2107. And, the burden is on the Examiner to establish that it is more likely than not that a person of ordinary skill in the art would not consider the asserted utilities to be specific, substantial, and credible. *See* M.P.E.P. § 2107 at 2100-30. Thus, "an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101." M.P.E.P. § 2107.02(III)(A) at 2100-39; *see also In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974).

The present specification (as also previously held by the Examiner parent application number 09/904,615 (now U.S. Patent No. 6,566,325)) fully and clearly sets forth Applicants' assertion that the polypeptides of the claimed invention have a specific and substantial, or a well-established utility. For example, the specification at page 159, lines 5-8, states that the claimed invention is useful, for example, in the detection of lung lymphoma. Furthermore, the specification discloses that the claimed protein may be used to raise antibodies as tissue markers and/or as a tumor marker (see page 159, lines 10-12 and lines 13-14 of the specification).

Moreover, in corroboration of this utility, Applicants respectfully direct the attention of the Examiner to the disclosure of the post-filing date publication, International Application No. WO 01/40466, published July 6, 2001 (previously cited in Applicants April 1, 2004 Supplemental Information Disclosure Statement as reference AB on Form PTO/SB/08). This publication discloses a protein referred to as PRO3743, which is 99% identical to the corresponding polypeptide sequence of SEQ ID NO:114 (*see* alignment previously submitted as Exhibit A on July 25, 2002 in parent application number 09/904,615). In addition, International Application No. WO 01/40466 discloses microarray data indicating that PRO3743 can be used in the diagnosis of lung cancer. (*See*, Table 8 on page 125, line 5 of WO 01/40466). Applicants submit that the disclosure of this publication corroborates assertions that the polypeptides of the invention, or antibodies against the polypeptides of the invention are useful, for example, in the diagnosis of lung lymphoma. (*See*, Applicants specification, page 159, lines 5-8).

Applicants reiterate that post filing date International Applications and scientific papers may be used to corroborate Applicants' asserted utility. Legal precedent for the use of post-filing date references in this manner can be found in *In re Brana*, where the courts stated:

> The Kluge declaration, though dated after applicants' filing date, can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification. *In re Marzocchi,* 439 F.2d at 224 n.4, 169 U.S.P.Q. (BNA) at 370 n.4.

See, In re Brana, 51 F.3d 1560 at 1567 n.19, 34 U.S.P.Q.2D (BNA) 1436 (March 30, 1995).

Applicants assert that one of ordinary skill in the art would consider the asserted utility of the invention, for example, as a lung lymphoma diagnostic marker, to be not only credible, but also *specific and substantial.* "When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. §101 is clearly shown." *Raytheon v. Roper*, 724 F.2d 951, 958 (Fed. Cir. 1983). Therefore, one of skill in the art would also consider that antibodies raised against the polypeptides of the invention to be specific (*e.g.*, the claimed invention is useful as a diagnostic marker for lung lymphoma), and substantial (*e.g.*, antibodies specific to the claimed polypeptides can indicate the presence or absence of lung lymphoma).

In view of the above, Applicants respectfully submit that a person of ordinary skill in the art would readily comprehend the instant invention to have a specific, substantial, and credible utility as appropriately disclosed in the specification as originally filed. Applicants, therefore, respectfully submit that the rejection of pending claims 25-40, 50-66, 69-83, 95-109, and 112-117 under 35 U.S.C. § 101 has been obviated and request that this rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 13, 25-41, 44-67, 69-84, 87-110, and 112-117 were rejected under 35 U.S.C. § 112, first paragraph, "since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above..." *See*, Paper No.20040610, page 7, part 11.

Applicants respectfully disagree and traverse the rejection. As an initial matter Applicants note that claims 13, 41, 44-49, 67, 84, 87-94, and 110 have been canceled herein. Therefore, the rejection with respect to these claims is now moot.

Additionally, in view of the evidence and explanations provided above, Applicants respectfully submit that the claimed invention is supported by "a specific and/or substantial asserted utility or a well established utility". Thus, a person of

ordinary skill in the art would know how to use the claimed invention without undue experimentation. Accordingly, it is respectfully requested that the rejection of pending claims 25-40, 50-66, 69-83, 95-109, and 112-117 be reconsidered and withdrawn.

A. Claims 13, 69, 87, and 95 were rejected based on assertion that:

> The reproduction of the polypeptide from the disclosed deposit No. 203081 is an extremely unpredictable event because it is known that bacteria contain[ing] multiple different clones with the same antibiotic [resistance gene] would lead to selective pressure favoring some clones over others and there is no guarantee that the cDNA encoding the polypeptide of SEQ ID NO:114 is going to be selected over time. The vector, [Uni-ZAP XR] comprising the cDNA encoding the polypeptide of SEQ ID NO:114, disclosed in table 1, page 174, 5th row of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. The instant specification does not disclose a repeatable process to obtain the vector...

See, Paper No.20040610, page 7, part 11.

Applicants respectfully disagree and traverse. The specification does, in fact, describe repeatable processes that can be used to obtain the cDNA encoding the polypeptide of SEQ ID NO:114 in ATCC Deposit No. 203081. In particular, Example 1, on page 364 to page 367 (line 17), describes two different methods, routinely understood and used by those of ordinary skill in the art, which can be used to isolate the target cDNA. The first method described is a screen whereby the plasmids are transformed into bacteria. The transformants are plated on 1.5% agar plates (containing the appropriate selection agent, *e.g.,* ampicillin) to a density of about 150 transformants (colonies) per plate. The plates are screened using Nylon membranes according to routine methods for bacterial colony screening (*e.g.*, Sambrook et al., Molecular Cloning: A Laboratory Manual, 2nd Edit., (1989), Cold Spring Harbor Laboratory Press, pages 1.93 to 1.104) and probed with a specific polynucleotide with 30-40 nucleotides labeled, for instance, with ^{32}P-γ-ATP using T4 polynucleotide kinase and purified according to routine methods. (*e.g.*, Maniatis et al., Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Press, Cold Spring, NY (1982).

Thus, Applicants note that since the above described method is a screen whereby bacteria transformed with the plasmid of interest are isolated and identified using a radiolabeled probe specific for the cDNA of interest, there is a "guarantee that the cDNA encoding the polypeptide of SEQ ID NO:114 is going to be selected" because *only* bacteria containing the correct plasmid *will be selected.* In other words, this method insures that only bacterial colonies containing the cDNA and plasmid of interest are selected for propagation. Moreover, one of ordinary skill in the art would also routinely perform any necessary subsequent verifications to have continued assurance that the correct cDNA and plasmid was being propagated (for example, by restriction enzyme digestion followed by agarose gel electrophoresis; *see* Sambrook *et al.*, Molecular Cloning: A Laboratory Manual, 2nd Edit., (1989)).

The second method described in the specification consists of a PCR amplification technique, which was also routinely performed by those of ordinary skill in the art as of the earliest claimed priority date in the present application. In this method the PCR amplified cDNA product is analyzed by agarose gel electrophoresis and the DNA band with the expected molecular weight is excised and purified. The PCR product is verified to be the selected sequence by subcloning and sequencing the DNA product. Hence, this method also insures that the correct cDNA is selected from the ATCC Deposit.

In consideration of the explanations and evidence provided above, it is respectfully requested that the rejection of pending claims 69 and 95 on the above asserted basis be reconsidered and withdrawn.

The Examiner has also requested submission of an affidavit or declaration with regard to the ATCC Deposit (which was made under terms of the Budapest Treaty). *See*, Paper No.20040610, page 7, part 11. Thus, Agent for the Applicant hereby attests to the statement provided herein, as evidenced by the signature below:

Availability of the Deposit

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on July 30, 1998, accepted by

> the ATCC, and given ATCC Accession Number 203081. The assignee understands its obligations under 37 C.F.R. §§ 1.805-1.808 with regard to the deposited biological material. And, in accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number 203081 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b).

In consideration of the explanations and evidence provided above, it is respectfully requested that the rejection of pending claims 25-40, 50-66, 69-83, 95-109, and 111-117, be reconsidered and withdrawn.

B. Claim 13 (dependent on claim 11) was also rejected under 35 U.S.C. § 112, first paragraph, based on a variety of asserted allegations. *See*, Paper No.20040610, pages 8-10, part 11B and 12. Without acquiescing to the asserted rejection, claim 13 has been canceled herein without prejudice or disclaimer. Hence, the rejection of this claim is now moot. Applicants reserve the right to pursue subject matter encompassed by all canceled claims in one or more divisional or continuation applications.

Claims 69-84 and 87-110 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *See*, Paper No.20040610, pages 9-10, part 12. In particular, it was asserted that:

> The ATCC deposit No. 203081 contains multiple different clones and it is unclear which protein, which the claimed antibodies bind to, is being referred to in the claims. Applicant has disclosed only amino acid of SEQ ID NO:114; therefore, the skilled artisan cannot envision all the contemplated amino sequence possibilities recited in the instant claims.

See, Paper No.20040610, pages 9-10, part 12.

As an initial matter Applicants note that claims 13, 84, 87-94, and 110 have been canceled herein. Therefore, the rejection with respect to these claims is now moot. Additionally, Applicants have herein amended pending claims 69 and 95 (and thus also the claims dependent thereon) to further clarify which protein is bound by

the claimed antibodies. In particular, these claims have been amended to specify that the claimed antibodies specifically bind the HUVDJ43 polypeptide encoded by the cDNA contained in ATCC Deposit Number 203081 wherein said HUVDJ43 polypeptide is at least 95% identical to SEQ ID NO:114. Support for this amendment can be found in the specification as filed, for example, at page 182, line 24 to page 183, line 2.

Accordingly, Applicants respectfully submit that the rejection of pending claims 69-83 and 95-109 has been accommodated. Therefore, it is respectfully requested that the rejection be reconsidered and withdrawn.

In view of the above, amendments, explanations, and evidence, Applicants submit that the rejection of claims 13, 25-41, 44-67, 69-84, 87-110, and 112-117, under 35 U.S.C. § 112, first paragraph, have been rendered moot, obviated, or accommodated. Accordingly, it is respectfully requested that the rejections be reconsidered and withdrawn.

Conclusion

Entry of the above amendments is respectfully requested. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if any fees not already accounted for are due in connection with the filing of this paper, please charge such fees to our Deposit Account No. 08-3425. If a fee not already accounted for is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: Dec. 13, 2004

Doyle A. Siever (Reg. No. 47,088)
Agent for Applicants

Human Genome Sciences, Inc.
Intellectual Property Department
14200 Shady Grove Road
Rockville, MD 20850
(301) 354-3932 (telephone)

KKH/DAS/mr